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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,541	12/19/2005	Amir Barzilay	15872.091	9957

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,541	BARZILAY ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/20/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *106,107 and 116-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *106,107 and 116-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments and amended claims filed on 11/20/09 is acknowledged.

Claims 88-96, 98-99, 101, 103-105 and 108-115 have been withdrawn.

Claims 97, 100 and 102 have been cancelled.

New claims 116-120 have been added.

Accordingly, claims **106-107 and 116-120** are under prosecution.

The following rejections are necessitated by applicant's amendments.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 106-107, 116, 118 and -120 are rejected under 35 U.S.C. 102(b) as being anticipated Rubin et al. (USP 5, 013, 569).

Rubin teaches a method of encapsulating bioactive materials such as immunoglobulins and omega-3 fatty acids and fortifying infant formula with the composition, abstract. Various methods for micro encapsulation are disclosed, such as forming micelles in water-in-oil emulsions, spray drying to make free particles, decreasing the solubility of a polymeric solution to induce coacervation, modifying the temperature of a polymeric solution until the polymer is no longer soluble and precipitates, interfacial polymerization, or the capsules can be formed in a dry blending process using free-flowable inclusion compounds such as cyclodextrins, see all of column 5 and column 6.

Rubin further teaches the infant formulation can be in the form of a concentrated powder or liquid, or in a ready to use form, see column 7, lines 15-17. Rubin teaches the inclusion of feed or food grade materials in the composition such edible fats, non-fat milk, peanut oil, soybean oil, whey, sugars, vitamins and minerals. Rubin discloses that acid milk whey contains beta lactoglobulins, immunoglobulins, and serum albumin. The formulation of the infant formula is intended to mimic human mother's milk. Humans are primates; this teaching therefore anticipates instant claims. The method also includes administering the formula composition to premature infants. Human milk is beneficial to

human infants and a composition with added imnmunoglobulins will help boost the infant's immunity, which would improve the health status of an infant, see whole of column 4, 7 , 8 and claims. The process of preparing in claims do not hold any patentable weight since the claims are drawn to method of improving health of infant by administering an encapsulated product. Burden is on applicant to show how the process changes the characteristics of the encapsulated product. Therefore the instant claims are anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 117 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al. (USP 5, 013, 569) in view of Paul (5,531,989).

The teachings of Rubin have been disclosed above. Rubin does not teach feed substitute as milk replacer or bioactive active ingredient as insulin.

Paul teaches the same ingredients for the production of a concentrate that contains milk protein, immunoglobulins, fiber, and other feed/food grade materials, see abstract. Paul teaches the use of carbohydrates such as maltodextrin in the composition, and the source of the immunoglobulin from milk products and whey,

column 4 lines 31-42. The immunoglobulin concentrate is formed by freeze-drying or spray drying methods, see lines 40-67 in column 8. Paul teaches the composition can be reconstituted in water or other liquids. Paul teaches incorporation of other bioactive compounds such as inulin in the composition.

It would have been obvious to have substituted feed grade milk replacer in the teachings of Rubin for therapeutic and nutritional benefits since such replacer is known in the art in feed formulation. It would be obvious to one of ordinary skill to incorporate the bioactive ingredient such as insulin in the microencapsulating process taught by Rubin because Paul teaches incorporation of bioactive compounds in feed which are helpful in gastrointestinal benefits. Utilization of any active ingredient which is beneficial to health would have been obvious to one of ordinary skill in the art in the teachings of Rubin's encapsulating process would have been obvious for better stability of feed ingredient absent evidence to contrary. It would also have been obvious to one of ordinary to utilize the known freeze drying process for forming the feed particles based on the teachings of Paul et al. and incorporate such process in producing encapsulated feed particles. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 106-107 and 116-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US 6,482,517) and Mandralis et al. (US 6,048,562).

Anderson et al. teach a method of making a coated particle in liquid phases of active compound and the encapsulating material. The compound to be encapsulated in the method of Anderson includes **a nucleic acid, a glycolipid, and a protein (reads on bioactive ingredient)** see claims 22, 23, 26 and 39. The release of the encapsulated agent is accomplished via a change in pH, pressure or temperature, see claims 50, 80, 82 and 83.

Anderson et al. do not teach mixing the bioactive compound with the encapsulant material to form a blend or other components instantly claimed as bioactive compounds or encapsulant material.

However, Mandralis et al. teach an encapsulation process by mixing a core material with an aqueous medium comprising a natural food polymer as an encapsulant, see the abstract and claim 1. The encapsulation material of Mandralis et al. is a natural food polymer, such as whey protein and egg white, see column 2, lines 31-43 and claim 5.

One of ordinary skill in the art at the time the invention was made would have been motivated to have mixed the encapsulating and core components of Anderson et al. by mixing the ingredients, as taught by Mandralis et al. to avoid the denaturation and chemical cross-liking processes, see column 1, lines 42-52 of Mandralis et al.

Although neither reference explicitly teaches adding the encapsulated materials to a food, feed or drink, Anderson et al. teach that encapsulating vegetable fats in cattle

feeds is a conventional practice in the art at the time the invention was made, see the discussion in the Background of the invention. In addition, one of ordinary skill in the art at the time the invention was made would have been motivated to have incorporated the encapsulated nutrients of Anderson et al. and Mandralis et al. to food, feed or drinks to stabilize the material and increase shelf-life, see column 1, lines 10-16 of Mandralis et al. Although the references do not exactly teach all the bioactive ingredients claimed, the reference does teach however encapsulation process of bioactive agents, thus utilization of specific bioactive agent in the combined teachings of the two references would have been obvious to one of ordinary skill in the art at the time of instant invention absent evidence of any unexpected results associated with specific bioactive ingredient.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art the time the invention was made, absent unexpected results to the contrary.

Applicant's arguments:

Applicant argues that Anderson teaches a method of making a coated particle in liquid phases of active compound and the encapsulated material and Mandralis et al. teach an encapsulating process by mixing a core material with an aqueous medium comprising a natural food polymer as an encapsulant, aimed at overcoming the need to employ denaturation at very high temperatures (100-180°C) and cross-linking. Applicant argues that the that the coated particles of Anderson and the methods for making them are significantly different from those of the present invention and states that the solution

provided by Mandralis et al. to avoid the denaturation and cross-linking is to use high pressure and a temperature up to 100°C, none of which are used, or suitable to be used according to the teachings of the present invention rather the presently claimed method specifically requires administration of heat-sensitive bioactive ingredients .to improve the health of the subject, wherein the bioactive ingredient must be encapsulated in a particular way to ensure the intended benefit. Applicant further argues that nowhere in Anderson and/or Mandralis method an improvement in the health status of a mammal is disclosed or even suggested and neither is the instant process disclosed.

Applicant's arguments are considered but are not persuasive. as discussed in the rejection above, the reference by Anderson teaches encapsulated protein which is a bioactive ingredient and suggests in the background section that encapsulated ingredients are given to cattles, thus the prior art teaches administration of encapsulated ingredient to animals. Secondary reference teaches encapsulation of food products for stabilization purposes. While it is true that none of the references teach process of improving health, however the references provide guidance to do so by disclosing method of encapsulating proteins and suggesting providing such product to animals for stability purposes. Regarding temperature limitations provided by Mandralis, it is position of the examiner that motivation to combine teachings of prior art does not have to be same as applicant's motivation to produce the invention. In the instant case one of ordinary would expect improvement in health by consuming proteins due to

therapeutic effects of the bioactive agent. It is to be noted that instant claims do not describe nature of improvement of health.

Applicant also argues that the instant application provides unexpected results that heat sensitive bioactive proteins, administered orally, maintained their activity and extent their effects to cause weight gain and further improvement in health of a mammal.

Applicants arguments do not commensurate with the scope of claims the instant claims are directed to any heat sensitive bioactive ingredient not just the bioactive proteins and secondly there is no recitation of oral administration recited in claims. Furthermore, it is not clear what applicant means by maintained their activity and in what sense the improvement in health was seen. Thus the unexpected results are specific to bioactive proteins as applicants themselves state in first paragraph of the response on page 9. The reference by Anderson does teach glycolipids and proteins and suggests in the background section the application of bioactive encapsulated ingredients in feed formulation; as such one of ordinary skill in the art would have envisaged encapsulating bioactive ingredients and administering the encapsulated ingredients to mammal for added stability of the product. One of ordinary would have expected benefits to health by administering such stable product by providing the non-denatured product. In the absence of specific health improvements defined in claims, it is the position of the examiner that the teachings of the references would have rendered the claimed invention obvious.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall
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/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612